

PATENT COOPERATION TREATY
PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference C07127	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/AU2007/001052	International filing date (day/month/year) 27 July 2007	(Earliest) Priority Date (day/month/year) 28 July 2006
Applicant RESMED LTD et al		
<p>This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.</p> <p>This international search report consists of a total of 6 sheets.</p> <p><input type="checkbox"/> It is also accompanied by a copy of each prior art document cited in this report.</p>		
<p>1. Basis of the report</p> <p>a. With regard to the language, the international search was carried out on the basis of:</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> The international application in the language in which it was filed.</p> <p style="margin-left: 40px;"><input type="checkbox"/> A translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).</p> <p>b. <input type="checkbox"/> This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).</p> <p>c. <input type="checkbox"/> With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.</p> <p>2. <input type="checkbox"/> Certain claims were found unsearchable (See Box No. II).</p> <p>3. <input checked="" type="checkbox"/> Unity of invention is lacking (See Box No. III).</p> <p>4. With regard to the title,</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> the text is approved as submitted by the applicant.</p> <p style="margin-left: 40px;"><input type="checkbox"/> the text has been established by this Authority to read as follows:</p> <p>5. With regard to the abstract,</p> <p style="margin-left: 40px;"><input checked="" type="checkbox"/> the text is approved as submitted by the applicant.</p> <p style="margin-left: 40px;"><input type="checkbox"/> the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.</p> <p>6. With regard to the drawings,</p> <p style="margin-left: 40px;">a. the figure of the drawings to be published with the abstract is Figure No. I-I</p> <p style="margin-left: 80px;"><input checked="" type="checkbox"/> as suggested by the applicant.</p> <p style="margin-left: 80px;"><input type="checkbox"/> as selected by this Authority, because the applicant failed to suggest a figure.</p> <p style="margin-left: 80px;"><input type="checkbox"/> as selected by this Authority, because this figure better characterizes the invention.</p> <p style="margin-left: 40px;">b. <input type="checkbox"/> none of the figures is to be published with the abstract.</p>		

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:

because they relate to subject matter not required to be searched by this Authority, namely:

2. ☐ Claims Nos.:

because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. ☐ Claims Nos.:

because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
See attached sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.: 1 to 17

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
- ☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
- ☐ No protest accompanied the payment of additional search fees.

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl.

A61M 16/00 (2006.01)

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

file dwpi: (a61m-016/ic or a62b-007/ic or a62b-009/ic or a62b-018/ic)

and (mask or interface) and (nasal or nose or nostril or nare or breath+ or face) and (cover or shield or enclos+ or overlay or protect+ or mask or encase+ or encapsul+ or guard or hold+ or retain+) and seal+

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2005099801 A1 (RESMED LIMITED) 27 October 2005 Whole description; in particular paragraphs [0078] to [0081]	1-6, 10-17
X	US 20050284481 A1 (MEYER) 29 December 2005 Whole description; in particular paragraphs [0011]	1-6, 12, 13, 16, 17
X	US 6968844 B2 (LILAND) 29 November 2005 Whole description; in particular column 3 lines 40 to 48	1, 12, 14



Further documents are listed in the continuation of Box C



See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"E" earlier application or patent but published on or after the international filing date

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"O" document referring to an oral disclosure, use, exhibition or other means

"A" document member of the same patent family

"P" document published prior to the international filing date but later than the priority date claimed

Date of the actual completion of the international search
9 October 2007

Date of mailing of the international search report

12 OCT 2007

Name and mailing address of the ISA/AU

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INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU2007/001052

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 20050061326 A1 (PAYNE) 24 March 2005 Whole description	
A	US 20030154980 A1 (BERTON-JONES) 21 August 2003 Whole description	

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: III

This International Application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept.

In assessing whether there is more than one invention claimed, I have given consideration to those features which can be considered to potentially distinguish the claimed combination of features from the prior art. Where different claims have different distinguishing features they define different inventions.

This International Searching Authority has found that there are different inventions as follows:

- Claims 1 to 17 which are directed to a patient interface comprising the features of a sealing arrangement, inlet conduit therefore and a cover which substantially encloses the sealing arrangement and or inlet conduit. It is considered that these features comprise a first distinguishing feature.
- Claims 18, 19 which are directed toward a method of fitting a patient interface comprising locating a sealing portion of the patient interface with respect to the patients nose and/or mouth and rotating or pivoting the patient interface about the sealing portion. It is considered that these features comprise a second distinguishing feature.

PCT Rule 13.2, first sentence, states that unity of invention is only fulfilled when there is a technical relationship among the claimed inventions involving one or more of the same or corresponding special technical features. PCT Rule 13.2, second sentence, defines a special technical feature as a feature which makes a contribution over the prior art.

The only feature common to all of the claims is a sealing portion of a patient interface. However this common feature is generic in the art. This means that the common feature can not constitute a special technical feature within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art.

Because the common feature does not satisfy the requirement for being a special technical feature it follows that it cannot provide the necessary technical relationship between the identified inventions. Therefore the claims do not satisfy the requirement of unity of invention *a posteriori*.

It is considered that search and examination for the second invention will require more than negligible additional search and examination effort over that for the first invention, and therefore an additional search fee is warranted.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU2007/001052

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report		Patent Family Member					
WO	2005099801	AU	2005232337	CN	1942215	EP	1740247
US	2005284481	FR	2872051				
US	6968844	AU	2003204201	EP	1371385	JP	2004008800
		NO	20022760	US	2003226564		
US	2005061326	US	6938620	US	2004025885		
US	2003154980	EP	0549299	EP	1149603	US	2002096173
		US	2007119454				
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.							
END OF ANNEX							

From the:
INTERNATIONAL SEARCHING AUTHORITY

To:

Halford & Co.
Level 7
1 Market Street
SYDNEY NSW 2000

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Date of mailing
(day/month/year)

Applicant's or agent's file reference
C07127

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/AU2007/001052

International filing date (day/month/year)

27 July 2007

Priority date (day/month/year)

28 July 2006

International Patent Classification (IPC) or both national classification and IPC
Int. Cl.

A61M 16/00 (2006.01)

Applicant

RESMED LTD et al

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA
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Date of completion of this opinion

9 October 2007

Authorized Officer

G.M. COX

AUSTRALIAN PATENT OFFICE
(ISO 9001 Quality Certified Service)
Telephone No. (02) 6283 2178

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ The international application in the language in which it was filed
 - ☐ A translation of the international application into, _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in electronic form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/AU2007/001052

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
☐ claims Nos: 18, 19

because:

- ☐ the said international application, or the said claim Nos.
relate to the following subject matter which does not require an international search (*specify*):

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos.
are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos.
are so inadequately supported by the description that no meaningful opinion could be formed (*specify*):

- ☒ no international search report has been established for said claims Nos. 18, 19

- ☐ a meaningful opinion could not be formed without the sequence listing; the applicant did not, within the prescribed time limit:

- ☐ furnish a sequence listing on paper complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
☐ furnish a sequence listing in electronic form complying with the standard provided for in Annex C of the Administrative Instructions, and such listing was not available to the International Searching Authority in a form and manner acceptable to it.
☐ pay the required late furnishing fee for the furnishing of a sequence listing in response to an invitation under Rule 13ter.1(a) or (b).

- ☐ a meaningful opinion could not be formed without the tables related to the sequence listings; the applicant did not, within the prescribed time limit, furnish such tables in electronic form complying with the technical requirements provided for in Annex C-bis of the Administrative Instructions, and such tables were not available to the International Searching Authority in a form and manner acceptable to it.

- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in electronic form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.
☐ See Supplemental Box for further details.

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-6, 10-17	YES
	Claims	NO
Inventive step (IS)	Claims	YES
	Claims 1-17	NO
Industrial applicability (IA)	Claims 1-17	YES
	Claims	NO

2. Citations and explanations:

The following documents identified in the International Search Report have been considered for the purposes of this report:

- D1: WO 2005099801 A1 (RESMED LIMITED) 27 October 2005
D2: US 20050284481 A1 (MEYER) 29 December 2005
D3: US 6968844 B2 (LILAND) 29 November 2005
D4: US 20050061326 A1 (PAYNE) 24 March 2005
D5: US 20030154980 A1 (BERTON-JONES) 21 August 2003

Documents D1 to D4 are relevant to the issue of novelty / inventive step and documents D4, D5 are "A" category documents merely illustrative of the state of the art.

Novelty (N): Claims

D1: Claims 1-6, 10-17

D1 discloses a conduit and cover arrangement for delivering gas to a nose piece. As shown in figure 1 the gas supply conduits (12) extend downwards on opposite sides of the patient's head and curve forwards towards their lower extremities. A cover of cloth or other material may be provided which will be comfortable to the patient and the cover may have decorative effects eg patterns or other markings which may be attractive to the child patient [00810]. It is implicit in this disclosure that the cover substantially covers the sealing arrangement (i.e. the headgear). Selected portions of the mask may have a thin layer of foam rubber or other suitable padding [0082]. The conduits are formed from plastic sheets (17) that are flocked (i.e. has a velvet like texture) so as to provide comfort to the patient [0081].

D2: Claims 1-6, 12, 13, 16, 17

D2 discloses a breathing mask in which the breathing gas is passed through the strap. The strap is of multilayer design; see [0009] for example. Consequently, the strap can be considered as an integral cover for the inlet conduit and its crosssectional area may vary [0011].

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of: BOX V

D3: Claims 1, 12, 14

D3 discloses a cover for a flexible patient breathing mask. The cover has the shape of a patient breathing mask and provides a tight fit of the mask against the patient's face. The cover has side edges for use by fastening devices. Given the shape of the cover and its deformability, it is reasonable to assume that in use it would not only enclose a substantial area of the mask but also because of its the fitment be an "organic" extension of the patient's face.

Inventive Step (IS): Claims 7 to 11

Inventive step: Claims 7 to 9

The features of these claims relate to matters of design choice which would be obvious to a person skilled in the art.

Inventive Step (IS): Claims 10, 11

These claims do not possess an inventive step in light of documents D1 to D3 cited above as the features of these claims are merely matters of design choice. Additionally, the features of colour, contrast, patterns etc do not provide for any functional relationship with the patient interface.

Industrial Applicability (IA)

The claims are related to products capable of commercial application.